**European Parliament**

*2019-2024*

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*Committee on the Environment, Public Health and Food Safety*

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**2020/0322(COD)**

30.4.2021

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**AMENDMENTS**

**103 - 302**

**Draft report**

Véronique Trillet-Lenoir

(PE689.812v01-00)

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Regulation on serious cross-border threats to health repealing Decision No 1082/2013/EU

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Proposal for a regulation

(COM(2020)0727 – C9-0367/2020 – 2020/0322(COD))
Amendment 103
Margrete Auken

Proposal for a regulation
Recital -1 (new)

Text proposed by the Commission

Amendment

(-1) The COVID-19 pandemic has highlighted the risks to human health posed by the over-exploitation of wildlife and other natural resources and the accelerated loss of biodiversity. As the health of humans, animals and the environment are inextricably linked, it is crucial to take the ‘One Health’ approach to address current and emerging crises. This is paramount as the majority (72%) of emerging diseases of humans, including COVID-19, influenza and HIV/AIDS, are caused by zoonotic pathogens.

Or. en

Amendment 104
Margrete Auken

Proposal for a regulation
Recital -1 a (new)

Text proposed by the Commission

Amendment

(-1 a) The Union’s ability to adequately respond to COVID-19 has been severely impeded by the absence of a clearly defined legal framework for managing its response to the pandemic, insufficient mandates of its health agencies and also by the limited degree of Union and Member State preparedness in case of a public health emergency impacting a majority of Member States.

Or. en
Amendment 105
Antoni Comín i Oliveres

Proposal for a regulation
Recital 1

Text proposed by the Commission

(1) A network for the epidemiological surveillance and control of communicable diseases was set up by Decision No 2119/98/EC of the European Parliament and of the Council. Its scope was extended by Decision No 1082/2013/EU of the European Parliament and of the Council to strengthen and provide for a further coordinated and wider approach to health security at Union level. The implementation of that legislation confirmed that coordinated Union action on monitoring, early warning of and combating those threats adds value to the protection and improvement of human health. The implementation of this legislation is another sign with which the Union is committed to the conclusions of the Global Conference on Primary Health Care of Astana of 25 and 26 October 2018.


Amendment

(1) A network for the epidemiological surveillance and control of communicable diseases was set up by Decision No 2119/98/EC of the European Parliament and of the Council. Its scope was extended by Decision No 1082/2013/EU of the European Parliament and of the Council to strengthen and provide for a further coordinated and wider approach to health security at Union level. The implementation of that legislation confirmed that coordinated Union action on monitoring, early warning of and combating those threats adds value to the protection and improvement of human health.


Or. en
Proposal for a regulation
Recital 1a (new)

Text proposed by the Commission

(1a) Among the most dangerous pathogens are the respiratory viruses, including orthopoxviruses such as smallpox, or novel influenzas, and coronaviruses. The Union, through its capabilities and know-how, should counter all these potential threats.

Amendment

Or. en

Amendment 107
Margrete Auken

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human

Amendment

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation between Member States, and Union agencies, particularly the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and international organisations, namely the World Health Organization (WHO). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of
The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.

Amendment 108
Joanna Kopcińska

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies while respecting the data protection rules.

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Or. en
Amendment 109
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 2

**Text proposed by the Commission**

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.

**Amendment**

(2) In light of the lessons learnt during the ongoing COVID-19 pandemic and in order to facilitate adequate Union-wide \textit{prevention}, preparedness and response to all cross-border threats to health, the legal framework for epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, as set out in Decision No 1082/2013/EU, needs to be broadened with regard to additional reporting requirements and analysis on health systems indicators, and cooperation by Member States with the European Centre for Disease Prevention and Control (ECDC). Moreover, in order to ensure effective Union response to novel cross-border threats to health, the legal framework to combat serious cross-border threats to health should enable to immediately adopt case definitions for the surveillance of novel threats and should provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin. The capacity for contact tracing should be strengthened via the creation of an automated system, using modern technologies.

Or. en

Amendment 110
Antoni Comín i Oliveres

Proposal for a regulation
Recital 2 a (new)
(2 a) It is therefore necessary that the Union be a full-fledged complementary component of European health systems, providing a guarantee or a last-resource stakeholder in case of serious cross-border health threats. For this reason, the know-how, expertise and capabilities of Union agencies should be strengthened accordingly.

Or. en

Amendment 111
Antoni Comín i Oliveres
Proposal for a regulation
Recital 2 b (new)

(2 b) Knowing that the SARS-CoV-2 virus has been uncannily good at disrupting cellular programming, the Union should prepare itself for all those serious cross-border threats that could have the same levels of cellular disruption, for which the sufficient and most reliable research and capabilities should be deployed.

Or. en

Amendment 112
Antoni Comín i Oliveres
Proposal for a regulation
Recital 2 c (new)

(2 c) In October, 2019, the first Global Health Security Index reported of a world largely unprepared to deal with a pandemic. Inter alia, it stated that there
was a lack of political will for accelerating health security in a perpetual cycle of panic and neglect, and that no country was fully prepared. With the current legislation, which builds upon the lessons-learned during the management of the COVID–19 pandemic, the Union wishes to amend this situation and prepare itself for future serious cross-border threats that may originate in epidemics or pandemics.

Amendment 113
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 3

Text proposed by the Commission

(3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health.

Amendment

(3) An important role in the coordination of prevention, preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health and support better coordination between Member States to address these threats.

Amendment 114
Antoni Comín i Oliveres

Proposal for a regulation
Recital 3
(3) An important role in the coordination of preparedness and response planning for serious cross-border threats to health is being played by the Health Security Committee (HSC), as formally established by Decision No 1082/2013/EU. This Committee should be given additional responsibilities with regard to the adoption of guidance and opinions to better support Member States in the prevention and control of serious cross-border threats to health.

The European Parliament should nominate observers for the HSC.

Amendment 115
Antoni Comín i Oliveres

Proposal for a regulation
Recital 4 a (new)

(4 a) There is plenty of scientific evidence that shows that health prevention and promotion policies (public health policies) are central to guaranteeing the right to health of citizens, and those are also the most efficient in terms of cost effectiveness. However, even today most of the budgets of the health systems of the majority of Member States are given very little space to policies for disease prevention and health promotion. The COVID-19 pandemic has firmly confirmed the importance of public health policies for our societies.
Proposal for a regulation  
Recital 4 b (new)  

Text proposed by the Commission  

(4 b) It is necessary to remember that these prevention and promotion strategies concern all sectoral policies: fiscal, commercial, economic, agro-environmental, educational, housing, cultural, social assistance, etc. Health in all policies (HiAP) should be a non-negotiable principle of all public policies. An instrument already used at the national level is the so-called Health Test to assess the health impact of the different sectoral policies. It is necessary to deploy a Health Test methodology in all the programmes managed by the Union.

Amendment 117  
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai  

Proposal for a regulation  
Recital 5  

Text proposed by the Commission  

(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.

Amendment  

(5) This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature, such as the International Health Regulations (IHR) of the World Health Organization (WHO) amongst others. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells,
This Regulation should apply without prejudice to other binding measures concerning specific activities or quality and safety standards for certain goods, which provide for special obligations and tools for monitoring, early warning and combatting specific threats of a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.
a cross-border nature. Those measures include, in particular, relevant Union legislation in the area of common safety concerns in public health matters, covering goods such as pharmaceutical products, medical devices and foodstuffs, substances of human origin (blood, tissues and cells, organs), and exposure to ionising radiation.

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States.

Amendment

Amendment 120
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Buşoi

Proposal for a regulation
Recital 6

Amendment

(6) In line with the "One Health" and "Health in all policies" approaches, the protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. The Union should urge Member States to implement the health-specific country-specific recommendations and support Member States to strengthen the resilience, responsiveness and readiness of healthcare systems in order to address future challenges, including pandemics. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the
through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

Amendment 121
Antoni Comín i Oliveres

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States.

Amendment

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States.
through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

All actions should be consistent with the WHO’s One Health approach, as well as with the Health in All Policies principle, recognising the interconnections between human and animal health and the environment and the cross-sectoral character of health policies.

Amendment 122
Joanna Kopcińska

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No

Amendment

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The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States and all relevant stakeholders, such as industry, supply chain actors, health professionals and patients associations, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.
Amendment 124
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation

Recital 6

Text proposed by the Commission

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

Amendment

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities and should ensure a “One Health” and “Health in all policies” approach. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.
Aldo Patriciello

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

Amendment

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, as well as in close dialogue with industry and supply chain actors, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

Or. en

Amendment 126
Danilo Oscar Lancini

Proposal for a regulation
Recital 6

Text proposed by the Commission

Amendment
The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

Or. en

Amendment 127
Margrete Auken

Proposal for a regulation
Recital 6

Text proposed by the Commission

(6) The protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid any overlap of activities, duplication or conflicting actions, the Commission, in

Amendment

(6) In line with the One Health and Health in All Policies approach, the protection of human health is a matter which has a cross-cutting dimension and is relevant to numerous Union policies and activities. In order to achieve a high level of human health protection, and to avoid
liaison with the Member States, should ensure coordination and exchange of information between the mechanisms and structures established under this Regulation, and other mechanisms and structures established at Union level and under the Treaty establishing the European Atomic Energy Community (the Euratom Treaty), the activities of which are relevant to the preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health. In particular, the Commission should ensure that relevant information from the various rapid alert and information systems at Union level and under the Euratom Treaty is gathered and communicated to the Member States through the Early Warning and Response System (‘EWRS’) set up by Decision No 2119/98/EC.

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Or. en

Amendment 128
Antoni Comín i Oliveres

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission

(6 a) Demographic change and technological innovation are some of the most important challenges facing our health systems. The aging of the population is largely due to the success of our healthcare systems and forces them, at the same time, to a structural transformation: from a healthcare model focused mainly on acute diseases, a shift is needed towards a healthcare model in which chronic diseases gain more weight and pandemics’ risk is significantly reduced. It is important that the Member States accompany each other in this
The process of transformation of the healthcare model, and for this reason it is necessary to strengthen good practices exchanging mechanisms.

Amendment 129
Kateřina Konečná

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combating serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Amendment

(7) Prevention, preparedness and response planning are essential elements for effective monitoring, early warning of and combating serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ prevention, preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. This training should be consistent with the One-Health approach in recognition of the interlinks between human health, animal health and the environment. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Specific considerations should be given to border regions, where joint cross-border exercises should be promoted and familiarity with the public
health system structures encouraged. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Amendment 130
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Amendment

(7) Preventing, preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. This exercise should be consistent with the One-Health approach in recognition of the interlinks between human health, animal health and the environment. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Specific considerations should be given to border regions, where joint cross-border exercises should be
Promoted and familiarity with the public health system structures encouraged.

Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Amendment 131
Margrete Auken

Proposal for a regulation
Recital 7

Amendment

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Text proposed by the Commission

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should include recommendations for policy interventions related to mitigation of the impact of communicable diseases on health services and care, including for non-communicable diseases (NCDs). The plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following
Amendment 132
Antoni Comín i Oliveres

Proposal for a regulation
Recital 7

Text proposed by the Commission

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. Where appropriate, regional authorities should participate in the drawing of these plans. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies, facilitating the sharing of best practices. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Amendment

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. Where appropriate, regional authorities should participate in the drawing of these plans. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies, facilitating the sharing of best practices. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.
Amendment 133
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat,
Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu
Buşoi

Proposal for a regulation
Recital 7

**Text proposed by the Commission**

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

**Amendment**

(7) *Prevention,* preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the HSC. This should be coupled with updates to Member States’ *prevention,* preparedness and response plans so as to ensure they are compatible within the regional level structures. *Particular attention must be paid to cross-border regions.* To support Member States in this endeavour, *the Commission and Union agencies should provide* targeted training and *facilitate the sharing of best practices* for healthcare staff and public health staff *to improve their* knowledge and ensure necessary skills. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.
Amendment 134  
Stanislav Polčák  
Proposal for a regulation  
Recital 7  

Text proposed by the Commission  

(7) Preparedness and response planning are essential elements for effective monitoring, early warning of and combatting serious cross-border threats to health. As such, a Union health crisis and pandemic preparedness plan needs to be established by the Commission and approved by the Health Security Committee (HSC). The abbreviation is used for the first reference and is not clear. This should be coupled with updates to Member States’ preparedness and response plans so as to ensure they are compatible within the regional level structures. To support Member States in this endeavour, targeted training and knowledge exchange activities for healthcare staff and public health staff should be provided knowledge and necessary skills should be provided by the Commission and Union Agencies. To ensure the putting into operation and the running of these plans, the Commission should conduct stress tests, exercises and in-action and after-action reviews with Member States. These plans should be coordinated, be functional and updated, and have sufficient resources for their operationalisation. Following stress tests and reviews of the plans, corrective actions should be implemented and the Commission should be kept informed of all updates.

Amendment 135  
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat,  

Or. cs
Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Buşoi

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission  

Amendment

(7 a)  Experience from the ongoing COVID-19 crisis has demonstrated that there is a need for a further firmer action at Union level to support cooperation and coordination among the Member States, in particular between neighbouring border regions. The national plans of Member States sharing a border with at least one other Member State must therefore include plans to improve the preparedness, prevention and response to health crises in border areas in neighbouring regions, including through mandatory cross-border training for healthcare staff and coordination exercises for the medical transfer of patients. The Commission should regularly report on the state of play of cross-border crisis preparation in neighbouring regions.

Or. en

Amendment 136  
Antoni Comín i Oliveres

Proposal for a regulation
Recital 7 a (new)

Text proposed by the Commission  

Amendment

(7 a)  Preparedness and response planning are also essential elements in order to prevent a “doom loop” situation, namely a cycle of negative economic feedback. When the COVID–19 pandemic hit, the world suffered a supply shock, where trade was disrupted, factories and stores closed, then salaries were in danger, the supply shock could turn into a
demand shock, and that would further weaken supply, which would increase unemployment and further diminish demand. In order to prevent a subsequent doom loop, the Union should make high-quality preparedness and response planning.

Amendment 137
Antoni Comín i Oliveres
Proposal for a regulation
Recital 7 b (new)

Text proposed by the Commission
Amendment

(7 b) Ensuring supply chain resilience across the Union is not a primordial mission of the Centre, yet the ECDC can provide data, knowledge, and skills, to the Commission and the EMA in order to ensure supply chain resilience in Europe. Supply chain resilience is part of the four working groups of the COVID-19 taskforce of the EMA, alongside the therapeutic response, business continuity and impact, and human resources.

Amendment 138
Antoni Comín i Oliveres
Proposal for a regulation
Recital 7 c (new)

Text proposed by the Commission
Amendment

(7 c) It is therefore necessary that the European Medicines Agency (EMA) assist the Commission in assessing the supply chain resilience of these products and devices in order to achieve a sufficient strategic autonomy of the Union.
in health products and devices. Ensuring supply chain resilience across the Union is not a primordial mission of this authority, yet the EMA should provide data, knowledge, and skills, to the Commission and the ECDC in order to ensure supply chain resilience in Europe. Supply chain resilience is part of the four working groups of the COVID–19 taskforce of the EMA, alongside the therapeutic response, business continuity and impact, and human resources.

Amendment 139
Margrete Auken

Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)\(^\text{15}\). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy,

Amendment

(8) Access to timely and complete data is a precondition for a rapid risk assessments and crisis mitigation. To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)\(^\text{15}\). To avoid duplication of efforts and diverging recommendations, standardised definitions and fluid information exchange should take place between Union agencies, the WHO and national agencies. In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national
transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.


Amendment 140
María Soraya Rodríguez Ramos, Jordi Cañas

Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) To this end,Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)\(^\text{15}\). In turn, the

Amendment

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level, \textit{including information on their strategic stockpiles and medical countermeasures available}. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the
Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.


Amendment 141
Antoni Comín i Oliveres
Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) To this end, Member States should provide the Commission with an update on

Amendment

(8) To this end, Member States should provide the Commission with an update on
the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.


Amendment 142
Danilo Oscar Lancini
Proposal for a regulation
Recital 8

Text proposed by the Commission

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)\(^\text{15}\). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

Amendment

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)\(^\text{15}\). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

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\(^{15}\) World Health Organization. International Health Regulation (IHR, 2005)
https://www.who.int/ihr/publications/9789241596664/en/
Amendment 143  
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 8

**Text proposed by the Commission**

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)\(^1\)\(^5\). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.

**Amendment**

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their *prevention*, preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)\(^1\)\(^5\). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with *prevention*, preparedness, response planning and implementation at Union level, including on corrective actions, every year to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.
(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR)\(^\text{15}\). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy, transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential...
services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.


Amendment 145
Joanna Kopcińska

Proposal for a regulation
Recital 8

**Text proposed by the Commission**

(8) To this end, Member States should provide the Commission with an update on the latest situation with regard to their preparedness and response planning and implementation at national level. Information provided by the Member States should include the elements that Member States are obliged to report to the World Health Organization (WHO) in the context of the International Health Regulations (IHR). In turn, the Commission should report to the European Parliament and to the Council on the state of play and progress with preparedness, response planning and implementation at Union level, including on corrective actions, every 2 years to ensure that national preparedness and response plans are adequate. In order to support the assessment of these plans, *EU audits in Member States should be conducted, in coordination with the ECDC and Union agencies. Such planning should include in particular adequate preparedness of critical sectors of society, such as energy,*
transport, communication or civil protection, which rely, in a crisis situation, on well-prepared gender-sensitive public health systems that are also in turn dependent on the functioning of those sectors and on maintenance of essential services at an adequate level. In the event of a serious cross-border threat to health originating from a zoonotic infection, it is important to ensure the interoperability between health and veterinary sectors for preparedness and response planning.


Amendment 146
María Soraya Rodríguez Ramos, Jordi Cañas

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8 a) The role of frontline health professionals has also become apparent during the pandemic as they have been key to ensuring access to medicine and continuity of care, providing moral support and being a source of trusted information against false information. For future emergencies, it is necessary to strengthen health professionals by laying down rules to provide training for workers in the fields of health care and public health. It is also necessary to integrate them through their professional organisations in the definition of public health policies as well as in the digital transformation in order to improve the quality and efficiency of health systems and ensure their sustainability for health, social and territorial cohesion work they
Amendment 147
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8 a) Health literacy plays a fundamental role in preventing and mitigating the impact of cross-borders threats and contributing to a better understanding by the population of the countermeasures and risk assessment of different threats. Respiratory etiquette, correct hand washing, avoiding unnecessary close contact with anyone with flu-like symptoms, and avoiding unprotected contact with wild animals should be part of health education campaigns to improve the population's behaviour, based on the latest available evidence.

Amendment

Or. en

Amendment 148
Margrete Auken

Proposal for a regulation
Recital 8 a (new)

Text proposed by the Commission

(8 a) Building on lessons learnt from the COVID-19 pandemic, this Regulation should create a more robust mandate for coordination at EU-level. The declaration of an EU emergency situation would trigger increased coordination and allow for timely development, stockpiling and joint procurement of medical...
Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council.

Amendment

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing and participating in any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council.

During a health crisis situation, manufacturing is often needed rapidly and at short notice. It is therefore crucial that the joint procurement lead times are aligned and coherent with manufacturers’ lead times to ensure clarity and expectations from both organizing and
participating entities. Regulatory flexibility should be considered and allowed to ensure faster supply to the markets, for example by accepting each other Marketing Authorizations in case of emergencies.

Joint procurement implies shared responsibilities and a fair approach with rights and obligations for all parties involved, relevant authorities and manufacturers. In this respect, commitments should be defined since the beginning and respected, from them manufacturers to deliver on the production, and from the authorities to purchase their agreed reserved volumes. This is also important to avoid wasting medicinal products.


Amendment 150
Pietro Fiocchi
Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU,

Amendment

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU,
should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council\(^\text{16}\). The exclusivity clause should entail that countries participating in the joint procurement procedure are not allowed to negotiate and sign parallel contracts with producers, and define clear consequences for those that do. The Commission should ensure coordination and information exchange between the entities organizing and participating in any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council.

"National stockpiles should be coordinated and discouraged in view of the creation of an EU strategic reserve of medical countermeasure and to prevent imbalances in the internal market. The functioning of the Joint Procurement Agreement and rescEU should abide by high standards of transparency, including in relation to the disclosure of the exact amount ordered and provided to each participating country, and delivery of procured products, and details of the liability of participating countries."


Amendment 151
Petar Vitanov

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council\(^\text{16}\).

Amendment

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. Countries participating in the joint procurement procedure shall not negotiate and sign parallel contracts with producers. The Commission should ensure coordination and information exchange between the entities organizing and participating in any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council\(^\text{16}\).

National stockpiles should be coordinated in view of the creation of a common EU strategic reserve of medical countermeasure and to prevent imbalances in the internal market. The functioning of the Joint Procurement Agreement and rescEU should abide by high standards of transparency, including in relation to the disclosure of the exact amount ordered and provided to each participating country, and delivery of procured products, and details of the liability of participating countries.
Amendment 152
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ștefan Motreanu, Cristian-Silviu Busoi

Proposal for a regulation
Recital 9

Text proposed by the Commission

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council.  

Amendment

(9) As serious cross-border threats to health are not limited to Union borders, the Union should adopt a coordinated approach in fighting against such threats. The joint procurement of medical countermeasures should, therefore, be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. In times of crisis, the Union should also aim to support access to medical countermeasures for Eastern Partnership and low- and middle-income countries. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures.
countermeasures, such as the strategic 
rescEU reserve under Decision No 
1313/2013/EU of the European Parliament 
and of the Council\textsuperscript{16}. The Member States 
should ensure a sufficient reserve of 
critical medical products at Member State 
level to counter the risk of shortages of 
critical products.

\textsuperscript{16} Decision No 1313/2013/EU of the 
European Parliament and of the Council of 
17 December 2013 on a Union Civil 
Protection Mechanism (OJ L 347, 

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Amendment 153
Margrete Auken

Proposal for a regulation
Recital 9

\textit{Text proposed by the Commission}

(9) As serious cross-border threats to 
health are not limited to Union borders, 
joint procurement of medical 
countermeasures should be extended to 
include European Free Trade Association 
States and Union candidate countries, in 
accordance with the applicable Union 
legislation. The Joint Procurement 
Agreement, determining the practical 
arrangements governing the joint 
procurement procedure established under 
Article 5 of Decision No 1082/2013/EU, 
should also be adapted to include an 
exclusivity clause regarding negotiation 
and procurement for participating countries 
in a joint procurement procedure, to allow 
for better coordination within the EU. The 
Commission should ensure coordination 
and information exchange between the 
entities organizing any action under 
different mechanisms established under 
this Regulation and other relevant Union

\textit{Amendment}

(9) As serious cross-border threats to 
health are not limited to Union borders, 
joint procurement of medical 
countermeasures should be extended to 
include European Free Trade Association 
States and Union candidate countries, in 
accordance with the applicable Union 
legislation. \textit{Joint procurement of medical 
countermeasures will strengthen the 
purchasing power of participating 
countries, improve the security of supply 
and ensure equitable access to medical 
countermeasures against serious cross-
border threats to health.} The Joint 
Procurement Agreement, determining the 
practical arrangements governing the joint 
procurement procedure established under 
Article 5 of Decision No 1082/2013/EU, 
should also be adapted to include an 
exclusivity clause regarding negotiation 
and procurement for participating countries 
in a joint procurement procedure, to allow
structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council\(^\text{16}\) for better coordination within the EU. All Joint Procurement Agreements should adhere to the highest level of transparency to allow public scrutiny of the contracts. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council\(^\text{16}\). The Union should, in a spirit of solidarity, pre-allocate part of jointly procured products to low-and middle-income countries.


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**Amendment 154**

**Dolors Montserrat**

**Proposal for a regulation**

**Recital 9**

*Text proposed by the Commission*

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU,

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*Amendment*

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU,
should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council\textsuperscript{16}.

\begin{footnotesize}
\begin{enumerate}
\end{enumerate}
\end{footnotesize}

The functioning of the Joint Procurement Agreement and rescEU should abide by high standards of transparency, including in relation to the disclosure of the exact amount ordered and provided to each participating country, and the delivery of procured products, and details of the liability of participating countries;

\begin{footnotesize}
\begin{enumerate}
\end{enumerate}
\end{footnotesize}

Or. en

\section*{Amendment 155
Antoni Comín i Oliveres
Proposal for a regulation
Recital 9

\begin{footnotesize}
\textit{Text proposed by the Commission}
\end{footnotesize}

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union

\begin{footnotesize}
\textit{Amendment}
\end{footnotesize}

(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union
legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council\textsuperscript{16}.


\textbf{Amendment 156}
\textbf{Joanna Kopcińska}

\textbf{Proposal for a regulation}
\textbf{Recital 9}

\textit{Text proposed by the Commission}

(9) As serious cross-border threats to health are not limited to Union borders,

\textit{Amendment}

(9) As serious cross-border threats to health are not limited to Union borders,
joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council.


Amendment 157
Pietro Fiocchi
Proposal for a regulation
Recital 9

Text proposed by the Commission

Amendment
(9) As serious cross-border threats to health are not limited to Union borders, joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council \(^\text{16}\).


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**Amendment 158**

Alessandra Moretti

**Proposal for a regulation**

Recital 9

*Text proposed by the Commission*

(9) As serious cross-border threats to health are not limited to Union borders,

*Amendment*

(9) As serious cross-border threats to health are not limited to Union borders,
joint procurement of medical countermeasures should be extended to include European Free Trade Association States and Union candidate countries, in accordance with the applicable Union legislation. The Joint Procurement Agreement, determining the practical arrangements governing the joint procurement procedure established under Article 5 of Decision No 1082/2013/EU, should also be adapted to include an exclusivity clause regarding negotiation and procurement for participating countries in a joint procurement procedure, to allow for better coordination within the EU. The Commission should ensure coordination and information exchange between the entities organizing any action under different mechanisms established under this Regulation and other relevant Union structures related to procurement and stockpiling of medical countermeasures, such as the strategic rescEU reserve under Decision No 1313/2013/EU of the European Parliament and of the Council\textsuperscript{16}.


Amendment 159
Danilo Oscar Lancini
Proposal for a regulation
Recital 9 a (new)

\textit{Text proposed by the Commission}

(9 a) Joint procurement should be limited to serious cross-border treats to health and should not impact pre-existing

Amendment

(9 a) Joint procurement should be limited to serious cross-border treats to health and should not impact pre-existing
contractual agreements with suppliers of medical countermeasures and should be carried in accordance with the Directive 2014/24/EU in a transparent manner, while respecting the following conditions: the procurement process, criteria, timelines, specifications, and formalities must be transparent and workable; a preliminary consultation phase involving potential participating manufacturers must take place; clear volume commitments irrespective of the selected supply modality must be ensured; participating countries need to commit not to procure the same medicines via other means; joint procurement lead times must be aligned with manufacturing processes lead times; national authorities should apply certain regulatory flexibilities; award criteria beyond price should be defined. Any joint procurement endeavour shall prevent market disruptions both in participating countries and other Member States not participating.

Amendment 160
Nathalie Colin-Oesterlé

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9a) In order to counteract not only the Union’s dependence on third countries but also the vicissitudes of manufacturing and disruptions in the supply chain, recalls the importance of diversified supplies and procurement practices for pharmaceuticals and the need to swiftly propose guidelines for the Member States, notably on how to best implement the most economically advantageous tender criteria, looking beyond the lowest price criterion only; investments in the manufacture of active ingredients and
medicinal end products in the EU should also be retained as a criterion, as well as the number and location of production sites, the reliability of supply, the reinvestment of profits into R&D and the application of social, environmental, ethical and quality standards;

Or. fr

Amendment 161
Joanna Kopcińska

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission Amendment

(9 a) Since one of the primary responsibility of the Member States is to ensure the protection of their citizens, additional flexibility is needed when it comes to being able to adjust contractual provisions after the initial contract has been established, in order to increase, decrease or cancel the order for the medical counter measures, taking into account significant changes in circumstances which may occur. In order to protect the contractors directly engaged in activities that serve Union policies, such contractual adjustments should be duly justified by the national authorities participating in the joint procurement procedure, by explaining the seriousness or urgency of the circumstances in question and such adjustments should be enforced in close cooperation with contracted partners and taking due account of the commitments made up to date of contractual adjustment.

Or. en

Amendment 162
Margrete Auken
Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9 a) Other mechanisms should be used to enable global response and crises mitigation. These include enhanced cooperation agreements on production of medical countermeasures, both voluntary and compulsory technology know-how pools and licensing agreements between companies. Triggering such mechanisms should guarantee equitable access to necessary counter-measures to global populations, including those in low-and middle-income countries.

Or. en

Amendment 163
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ștefan Motreanu, Cristian-Silviu Bușoi

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9 a) Joint procurement should be based on shared responsibilities and a fair approach for all parties involved, both relevant authorities and manufacturers. Clear commitments should be ensured and respected for all parties involved, from the manufacturers to deliver on the production, and from the authorities to purchase their agreed reserved volumes;

Or. en

Amendment 164
Pietro Fiocchi
Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9 a) The primary purpose of joint procurement should be to guarantee stability in an unpredictable environment in the context of a cross-border health crisis only, ensuring equitable access for patients and increased visibility and predictability for actors involved;

Amendment 165
Dolors Montserrat

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

(9 a) Regulatory flexibility should be considered and allowed to ensure faster supply to the markets of the different Member States, for example by accepting each other Marketing Authorizations in case of emergencies;

Amendment 166
Pietro Fiocchi

Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission

(9 b) The joint procurement shall be carried in a transparent, timely and effective way to prevent market disruption and to ensure actors involved can fulfil their contractual responsibilities. In this respect, it is crucial to define clear and
transparent steps since the beginning of the procedure in terms of process, scope, tender specifications, timelines and formalities. A preliminary consultation phase involving participating actors shall be guaranteed, as well as a two-way communication throughout the whole procedure;

Or. en

Amendment 167
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Bușoi

Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission

Amendment

(9 b) The joint procurement shall be carried in a transparent, timely and effective way to prevent market disruption and to ensure all actors involved shall fulfil their contractual responsibilities. Clear and transparent stages should be defined for the process, scope, specifications, timelines and formalities;

Or. en

Amendment 168
Dolors Montserrat

Proposal for a regulation
Recital 9 b (new)

Text proposed by the Commission

Amendment

(9 b) If joint deployment is deployed, qualitative criteria should also be considered in the awarding process in addition to cost. Such criteria should also take into consideration, for example, the ability of the manufacturer to ensure
security of supply during a health crisis;

Amendment 169
Pietro Fiocchi
Proposal for a regulation
Recital 9 c (new)

Text proposed by the Commission Amendment

(9 c) During a health crisis situation, manufacturing is often needed rapidly and at short notice. It is therefore crucial that the joint procurement lead times are aligned and coherent with manufacturers’ lead times to ensure clarity and expectations from both organizing and participating entities;

Amendment 170
Pietro Fiocchi
Proposal for a regulation
Recital 9 d (new)

Text proposed by the Commission Amendment

(9 d) Regulatory flexibility should be considered and allowed to ensure faster supply to the markets, for example by accepting each other Marketing Authorizations in case of emergencies;

Amendment 171
Pietro Fiocchi
Proposal for a regulation
Recital 9 e (new)
(9 e) Joint procurement implies shared responsibilities and a fair approach with rights and obligations for all parties involved, relevant authorities and manufacturers. In this respect, commitments should be defined from the beginning and respected, by the manufacturers to deliver on the production, and by the authorities to purchase their agreed reserved volumes. This is also important to avoid waste of medicinal products;

Or. en

Amendment 172
Pietro Fiocchi
Proposal for a regulation
Recital 9 f (new)

Text proposed by the Commission

(9 f) If used, in order for joint procurement to be sustainable, it is crucial to define criteria beyond the price/cost only to be considering in the awarding process. Such criteria should take into consideration for instance the ability of the bidder to ensure security of supply in a health crisis situation;

Or. en

Amendment 173
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Buşoi
Proposal for a regulation
Recital 10
Unlike for communicable diseases, the surveillance of which at Union level is carried out on a permanent basis by the ECDC, other potentially serious cross-border threats to health do not currently necessitate monitoring by EU Agencies. A risk-based approach, whereby monitoring is carried out by Member States and available information is exchanged through EWRS, is therefore more appropriate for such threats. Nevertheless, the ECDC should have the ability to monitor the impact of communicable diseases on non-communicable diseases, including the continuity of screening, diagnosis, monitoring, treatment and care in the healthcare system;
Amendment 175
Pietro Fiocchi

Proposal for a regulation
Recital 10 a (new)

Text proposed by the Commission

(10 a) An increasing number of Member States are seeking to establish national stockpiles of medical countermeasures, that generates a stark increase in demand as a result that far exceeds patient demand forecasts based on epidemiological need and create sudden large spikes in demand that can place considerable strain on suppliers and, as a result, lead to challenges in meeting demand in other countries and create imbalances in the internal market particularly affecting the smaller countries;

Amendment

Or. en

Amendment 176
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Buşoi

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

Amendment

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance. In times of crisis, particular attention should also be paid to the continuity of screening,
diagnosis, monitoring, treatment and care for other diseases and conditions, and to the mental health implications of the crisis and psychosocial needs of the population.

Amendment 177
Joanna Kopcińska

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

Amendment

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance or major non-communicable diseases.

Amendment 178
Margrete Auken

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

Amendment

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve, through the One Health approach, the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues,
such as antimicrobial resistance.

Amendment 179
Antoni Comín i Oliveres
Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance.

Amendment

(11) The Commission should strengthen cooperation and activities with the Member States, the ECDC, the European Medicines Agency (‘EMA’), other Union Agencies, research infrastructures and the WHO to improve the prevention of communicable diseases, such as vaccine preventable diseases, as well as other health issues, such as antimicrobial resistance, cancer, and mental health.

Amendment 180
Dolors Montserrat
Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then

Amendment

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and, together with pharmacies and other licensed health care establishments, also testing for assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin,
as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose. from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services, as well as pharmacy services and other licensed health services and establishments, and their authorities to serve this dual purpose.

Amendment 181
María Soraya Rodríguez Ramos, Jordi Cañas
Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose.

Amendment

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services, pharmacies and other licensed health care establishments in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities, as well as pharmacy services and other licensed health services and establishments, to serve this dual purpose.
Amendment 182
Sara Cerdas, Monika Beňová, Petar Vitanov, Sándor Rónai

Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose.

Amendment

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin or under a process of medically assisted reproduction, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national blood and transplant services and their authorities to serve this dual purpose.

Or. en

Amendment 183
Antoni Comín i Oliveres

Proposal for a regulation
Recital 12

Text proposed by the Commission

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and

Amendment

(12) In case of cross-border health threats due to a communicable disease, the blood and transplant services in the Member States can provide a means for rapid testing of the donor population and
assessing exposure to and immunity from the disease in the general population. These services in return are dependent on rapid risk assessments by the ECDC to safeguard patients, in need of a therapy from a substance of human origin, from a transmission of such communicable disease. Such risk assessment serves then as basis to allow for the appropriate adaptation of measures setting standards for quality and safety of such substances of human origin. The ECDC should therefore set up and operate a network of national and regional blood, plasma and transplant services and their authorities to serve this dual purpose.

Amendment 184
María Soraya Rodríguez Ramos, Jordi Cañas

Proposal for a regulation
Recital 12 a (new)

Text proposed by the Commission

(12 a) In order to improve early preparedness and response to the emergence of cross-border health threats, it is crucial to enable continuous and rapid access to data on the availability of the necessary medical countermeasures. Therefore, a network of Member States' services providing up-to-date information on national strategic stockpiles and the availability of medical countermeasures, stockpiles of medical products, essential health products and diagnostic tests should be established, operated and coordinated by the ECDC. Strengthening coordination and information with Member States on strategic stockpiles and medical countermeasures available is necessary to enhance the collection, modelling and use of prospective data that allows early alert notifications in the EU.
Amendment 185
Antoni Comín i Oliveres

Proposal for a regulation
Recital 13

Text proposed by the Commission

(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

Amendment

(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source. The notification system of the EWRS should be an electronic, digital, interoperable platform which may also be built upon distributed ledger technology (DLT) and include data from national and regional competent authorities. Finally, this platform should also be linked to the Health dataspace.
Amendment 186
Sara Cerda, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 13

*Text proposed by the Commission*

(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

*Amendment*

(13) A system enabling the notification at Union level of alerts related to serious cross-border threats to health has been put in place by Decision No 2119/98/EC in order to ensure that competent public health authorities in Member States and the Commission are duly informed in a timely manner. All serious cross-border threats to health covered by this Regulation are covered by the EWRS. The operation of the EWRS should remain within the remit of the ECDC. The notification of an alert should be required only where the scale and severity of the threat concerned are or could become so significant that they affect or could affect more than one Member State and require or could require a coordinated response at the Union level. To avoid duplication and ensure coordination across Union alert systems, the Commission and ECDC should ensure that alert notifications under the EWRS and other rapid alert systems at Union level are automatically linked to each other to the extent possible so that the competent authorities of the Member States can avoid as much as possible notifying the same alert through different systems at Union level and can benefit from receiving all-hazard alerts from a single coordinated source.

Amendment 187
Nathalie Colin-Oesterlé
Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

(13a) In order to enable medicinal products to be made available during the COVID19 pandemic, marketing authorisation holders were allowed regulatory flexibilities, by for example covering procedures for changes in the suppliers of active pharmaceutical ingredients, the designation of new manufacturing sites and faster import authorisations, in order to better mitigate the shortage of medicines. These solutions should be made permanent in order to be able to respond to future situations and these flexibilities should be applied by Member States in a consistent manner to avoid fragmentation of the internal market and ineffective outcomes.

Amendment 188
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ștefan Motreanu, Cristian-Silviu Bușoi

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

(13 a) Regular dialogue and exchange of information between authorities, industry, relevant entities of the pharmaceutical supply chain, healthcare professionals' and patients' organizations should also be ensured to start early discussions about expected potential serious cross-border threats to health in the market by way of sharing expected supply constraints or raising of specific clinical needs, allowing better coordination, synergies and appropriate reaction when needed.
Amendment 189
Aldo Patriciello

Proposal for a regulation
Recital 13 a (new)

Text proposed by the Commission

(13 a) Regular two-way communication and exchange of information between authorities, industry and relevant entities of the pharmaceutical supply chain should also be ensured to start early discussions about expected potential serious cross-border threats to health in the market by way of sharing expected supply constraints, allowing better coordination, synergies and appropriate reaction when needed.

Or. en

Amendment 190
Antoni Comín i Oliveres

Proposal for a regulation
Recital 14

Text proposed by the Commission

(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality

(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality
and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.

Amendment 191
Margrete Auken

Proposal for a regulation
Recital 14

Text proposed by the Commission

(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of excellence, independence, impartiality and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.

Amendment

(14) In order to ensure that the assessment of risks to public health at the Union level from serious cross-border threats to health is consistent as well as comprehensive from a public health perspective, the available scientific expertise should be mobilised in a coordinated and multidisciplinary manner, through appropriate channels or structures depending on the type of threat concerned. That assessment of risks to public health should be developed by means of a fully transparent process and should be based on principles of science, excellence, independence, impartiality and transparency. The involvement of Union agencies in these risk assessments needs to be broadened according to their speciality in order to ensure an all hazard approach, via a permanent network of agencies and relevant Commission services to support the preparation of risk assessments.
Amendment 192
Margrete Auken

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission

Amendment

(14 a) Member States, the Commission and Union agencies should identify recognised public health organisations and experts, both in the area of communicable and non-communicable diseases, and other relevant stakeholders across sectors, applying the One Health approach, available to assist in Union responses to health threats. Such experts and stakeholders, including civil society organisations, should be structurally engaged throughout all crisis response activities and contribute to the decision-making processes. Full compliance with transparency and conflict of interest rules for stakeholder engagement should be ensured.

Amendment 193
Antoni Comín i Oliveres

Proposal for a regulation
Recital 15

Text proposed by the Commission

Amendment

(15) The Member States have a responsibility to manage public health crises at national level. However, measures taken by individual Member States could affect the interests of other Member States if they are inconsistent with one another or based on diverging risk assessments. The aim to coordinate the response at Union level should, therefore, seek to ensure, inter alia, that measures taken at national level
are proportionate and limited to public health risks related to serious cross-border threats to health, and do not conflict with obligations and rights laid down in the Treaty on the Functioning of the European Union such as those related to free movement of persons, goods and services.

Amendment 194
Antoni Comín i Oliveres
Proposal for a regulation
Recital 16

**Text proposed by the Commission**

(16) To this effect, the HSC responsible for the coordination of response at Union level, should assume additional responsibility for the adoption of opinions and guidance for Member States related to the prevention and control of a serious cross border threats to health. Furthermore, should the coordination of national public health measures prove insufficient to ensure an adequate Union response, the Commission should further support Member States via the adoption of recommendations on temporary public health measures.

**Amendment**

(16) To this effect, the HSC responsible for the coordination of response at Union level, should assume additional responsibility for the adoption of opinions and guidance for Member States related to the prevention and control of a serious cross border threats to health. Furthermore, should the coordination of national and regional public health measures prove insufficient to ensure an adequate Union response, the Commission should further support Member States via the adoption of recommendations on temporary public health measures.

Or. en

Amendment 195
Stanislav Polčák
Proposal for a regulation
Recital 16

**Text proposed by the Commission**

(16) To this effect, the HSC responsible

**Amendment**

(16) To this effect, the HSC responsible
for the coordination of response at Union level, should assume additional responsibility for the adoption of opinions and guidance for Member States related to the prevention and control of a serious cross border threats to health. Furthermore, should the coordination of national public health measures prove insufficient to ensure an adequate Union response, the Commission should further support Member States via the adoption of recommendations on temporary public health measures.

Amendment 196
Antoni Comín i Oliveres
Proposal for a regulation
Recital 17

Text proposed by the Commission

(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil...
Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council. Given the cross-sectoral nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council.


Amendment 197
Margrete Auken
Proposal for a regulation
Recital 17

Text proposed by the Commission

(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust and independent evaluation of public health risks, to be adapted to national needs and circumstances. Such exchanges of information are intended to facilitate the monitoring of the clarity and coherence of messages to the public and to healthcare professionals. Given the cross-sectoral coherence of messages to the public and to healthcare professionals, the ECDC should broaden its communication activities to provide key information available in all EU languages to the general public and serve as a point of reference and reliable source of information. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust

Amendment

(17) Inconsistent communication with the public and stakeholders such as healthcare professionals can have a negative impact on the effectiveness of the response from a public health perspective as well as on economic operators. In addition to the recommendations targeted at Member States and healthcare professionals, the ECDC should broaden its communication activities to provide key information available in all EU languages to the general public and serve as a point of reference and reliable source of information. The coordination of the response within the HSC, assisted by relevant subgroups, should, therefore, encompass rapid information exchange concerning communication messages and strategies and addressing communication challenges with a view to coordinating risk and crisis communication, based on robust
nature of this type of crises, coordination should also be ensured with other relevant constituencies, such as the Union Civil Protection Mechanism established by Decision (EU) 2019/420 of the European Parliament and of the Council.


Amendment 198
Antoni Comín i Oliveres
Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the

Amendment

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level, taking into account the urgency of the situation where the Commission may have to recognise the public health emergency level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the
Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers, therefore without any type of decision-making competence in order to guarantee that the Commission can act accordingly to the urgent need of recognising the public health emergency at Union level. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Amendment 199
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dăn-Ştefan Motreanu, Cristian-Silviu Bușoi

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat

Amendment

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat
constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Or. en

Amendment 200
Stanislaw Polčák

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In

Amendment

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In
order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Member States, through their representatives, should also be able to participate in the Committee’s meetings as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Amendment 201
Aldo Patriciello

Proposal for a regulation
Recital 18

Text proposed by the Commission

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish

Amendment

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish
an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers with close involvement of the relevant industry stakeholders. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Or. en

Amendment 202
Danilo Oscar Lancini

Proposal for a regulation
Recital 18

Text proposed by the Commission

Amendment

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers with close involvement of the relevant industry stakeholders. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.
constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Amendment 203
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 18

Text proposed by the Commission
(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination

Amendment
(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination
of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for *medical* products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

**Amendment 204**

**Margrete Auken**

**Proposal for a regulation**

**Recital 18**

*Text proposed by the Commission*

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, selected by the Commission from the fields of expertise.

**Amendment**

(18) The recognition of public health emergency situations and the legal effects of this recognition provided by Decision No 1082/2013/EU should be broadened. To this end, this Regulation should allow for the Commission to formally recognise a public health emergency at Union level. In order to recognise such an emergency situation, the Commission should establish an independent advisory committee that will provide expertise on whether a threat constitutes a public health emergency at Union level, and advise on public health response measures and on the termination of this emergency recognition. The advisory committee should consist of independent experts, and representatives of civil society, selected by the Commission, *after consulting the Health Security Committee*, from the fields of expertise and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for *medicinal* products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.
and experience most relevant to the specific threat that is occurring, representatives of the ECDC, of the EMA, and of other Union bodies or agencies as observers. Recognition of a public health emergency at Union level will provide the basis for introducing operational public health measures for medical products and medical devices, flexible mechanisms to develop, procure, manage and deploy medical countermeasures as well as the activation of support from the ECDC to mobilise and deploy outbreak assistance teams, known as ‘EU Health Task Force’.

Amendment 205
Antoni Comín i Oliveres

Proposal for a regulation
Recital 19

*Text proposed by the Commission*

(19) Before recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission’s analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision. Where such a recognition is adopted, the Commission should also inform the WHO thereof.

*Amendment*

(19) Before recognising a situation of public health emergency at Union level, the Commission should liaise with the WHO in order to share the Commission’s analysis of the situation of the outbreak and to inform the WHO of its intention to adopt such a decision. Where such a recognition is adopted, the Commission should also inform the WHO thereof. *The liaison with the WHO should not question the Union’s strategic autonomy in countering the serious cross-border threats or outbreaks within its borders.*

Amendment 206
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 20

Text proposed by the Commission

(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease, between those Member States directly involved in the contact-tracing measures. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.

Amendment

(20) The occurrence of an event that corresponds to serious cross-border threats to health and is likely to have Union-wide consequences should require the Member States concerned to take particular control or contact-tracing measures in a coordinated manner in order to identify people already contaminated and those persons exposed to risk. Such cooperation could require the exchange of personal data through the system, including sensitive information related to health and information about confirmed or suspected human cases of the disease or infection, between those Member States directly involved in the contact-tracing. The exchange of personal data concerning health by the Member States has to comply with Article 9(2)(i) of Regulation (EU) 2016/679 of the European Parliament and of the Council.

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Or. en

Amendment 207
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 21

Text proposed by the Commission

(21) Cooperation with third countries and international organisations in the field

Amendment

(21) Cooperation with third countries and international organisations in the field
of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is also required to contribute to EU’s commitment to strengthening support to health systems and reinforcing partners’ preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health.

Within the limits of the Union’s competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response.

Amendment 208
Stanislav Polčák
Proposal for a regulation
Recital 21

Text proposed by the Commission

(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is

Amendment

(21) Cooperation with third countries and international organisations in the field of public health should be fostered. It is particularly important to ensure the exchange of information with the WHO on the measures taken pursuant to this Regulation. This reinforced cooperation is
also required to contribute to EU’s commitment to strengthening support to health systems and reinforcing partners’ preparedness and response capacity. The Union could benefit from concluding international cooperation agreements with third countries or international organisations, including the WHO, to foster the exchange of relevant information from monitoring and alerting systems on serious cross-border threats to health. Within the limits of the Union’s competences, such agreements could include, where appropriate, the participation of such third countries or international organisations in the relevant epidemiological surveillance monitoring network and the EWRS, exchange of good practice in the areas of preparedness and response capacity and planning, public health risk-assessment and collaboration on response coordination, including the research response.

Amendment 209
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Bușoi
Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission

(21 a) The Commission and the Member States should actively work towards a new global treaty for pandemic preparedness and response under the framework of the World Health Organization and with close involvement of other relevant organizations, building on and improving the existing global health instruments, especially the International Health Regulations (2005)\(^1\)\(^{a}\) to ensure a firm and tested foundation. Such a Treaty should support and focus on strengthening the
international health framework and improving cooperation with regard to early detection, prevention, response and resilience to future pandemics.

\[^{1a}\text{World Health Organization. International Health Regulation (IHR, 2005)}\]
https://www.who.int/ihr/publications/9789241596664/en/

Or. en

Amendment 210
Margrete Auken

Proposal for a regulation
Recital 22

*Text proposed by the Commission*

(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council\(^{19}\). In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.

*Amendment*

(22) *Due to the sensitive nature of the health data, Member States, the Commission and Union agencies should safeguard and guarantee that their processing operations respect the data protection principles of lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality.*

The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council\(^{19}\). In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.

*Article 27 of Regulation (EU) 2018/1725*
EUDPR should be strictly respected and appropriate technical and organisational security measures in accordance with Article 33 EUDPR should be put in place.


Amendment 211
Antoni Comín i Oliveres

Proposal for a regulation
Recital 22

Text proposed by the Commission

(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.

Amendment

(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national and regional level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.


Amendment 212
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 22

Text proposed by the Commission

(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing measures.

Amendment

(22) The processing of personal data for the purpose of implementing this Regulation should comply with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725 of the European Parliament and of the Council. In particular, the operation of the EWRS should provide for specific safeguards for the safe and lawful exchange of personal data for the purpose of contact tracing measures implemented by Member States at national level. In this regard, the EWRS includes a messaging function in which personal data, including contact and health data, can be communicated to relevant authorities involved in contact tracing.

Amendment 213
Antoni Comín i Oliveres

Proposal for a regulation
Recital 24

Text proposed by the Commission

(24) As responsibility for public health is not an exclusively national matter in certain Member States, but is substantially decentralised, national authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Regulation.

Amendment

(24) As responsibility for public health is not an exclusively national matter in certain Member States, but is substantially decentralised, national and regional authorities should, where appropriate, involve the relevant competent authorities in the implementation of this Regulation.

Or. en

Amendment 214
Kateřina Konečná

Proposal for a regulation
Recital 25

Text proposed by the Commission

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and,

Amendment

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and,
where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the functioning of the surveillance platform; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

Justification

To comply with the data protection principles of purpose limitation and data minimisation, avoiding disproportionate access by ECDC to patient data, a precise list of health data should be developed via an implementing act. Such act should also lay down the role that ECDC will assume when processing personal data (e.g. controller, processor or joint controller).

Amendment 215
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Recital 25

Text proposed by the Commission

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning;

Amendment

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information on preparedness and response planning;
organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the functioning of the surveillance platform; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

Amendment 216
Antoni Comín i Oliveres
Proposal for a regulation
Recital 25

Text proposed by the Commission

Amendment

(25) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to: templates to be used when providing the information

organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the establishment and update of a list of relevant health data to be automatically collected by digital platform; the functioning of the surveillance platform; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

Or. en
on preparedness and response planning; organisation of the training activities for health care and public health staff; the establishment and update of a list of communicable diseases and related special health issues subject to the network of epidemiological surveillance and the procedures for the operation of such a network; the adoption of case definitions for those communicable diseases and special health issues covered by the epidemiological surveillance network and, where necessary, for other serious cross-border threats to health subject to ad hoc monitoring; the procedures for the operation of the EWRS; the functioning of the surveillance platform; the designation of EU reference laboratories to provide support to national reference laboratories; the procedures for the information exchange on and the coordination of the responses of the Member States; the recognition of situations of public health emergency at Union level and the termination of such a recognition and procedures necessary to ensure that the operation of the EWRS and the processing of data are in accordance with the data protection legislation.

Or. en

Amendment 217
Kateřina Konečná

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission

(25 a) National authorities should where appropriate consult and involve in the implementation of this regulation representatives of patients organisations and national social partners in the healthcare and social services sector.

Or. en
Amendment 218
Kateřina Konečná
Proposal for a regulation
Recital 25 b (new)

*Text proposed by the Commission*

(25 b) The recommendations of the World Health Organization’s High Level Expert Group on Health Employment and Economic Growth to address workforce shortages shall be integrated in the prevention, preparedness and response plans to ensure adequate and needs-oriented staffing level.

*Amendment*

1a [https://www.who.int/hrh/com-heeg/reports/report-expert-group/en/](https://www.who.int/hrh/com-heeg/reports/report-expert-group/en/)

Or. en

Amendment 219
Antoni Comín i Oliveres
Proposal for a regulation
Recital 28

*Text proposed by the Commission*

(28) In order to ascertain the state of implementation of the national and regional preparedness plans and their coherence with the Union plan, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of procedures, standards and criteria for the audits aimed at the assessment of preparedness and response planning at national and regional level. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be...
conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

Audit

__________________


Amendment 220
Kateřina Konečná

Proposal for a regulation
Recital 28 a (new)

*Text proposed by the Commission*

(28 a) The COVID-19 health crisis has shown that neither the joint procurement of medical countermeasures nor Union funding for research into them have proved to be a sufficient solution to tackle the public health emergency. In the event that a public health emergency is declared at Union level and instruments under this regulation, such as joint procurement of medical countermeasures, will prove that are not sufficient to address the health crisis, the Commission should in the future have the power in line with the WTO rules to grant so-called compulsory licenses on patents on these medicines, vaccines and medical devices to Union manufacturers to enhance Union production capacity. Asks the Commission and the Member States to consider the possible delegation of power to grant compulsory licenses to the Commission in the next revision of this Regulation.

*Amendment*

Or. en
Amendment 221
Antoni Comín i Oliveres

Proposal for a regulation
Article 1 – paragraph 1 – point b – point i

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(i) preparedness plans at Union and national levels;</td>
<td>(i) preparedness plans at Union and national and regional levels;</td>
</tr>
</tbody>
</table>

Amendment 222
Joanna Kopcińska

Proposal for a regulation
Article 1 – paragraph 1 – point b – point ii

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(ii) reporting and auditing on preparedness;</td>
<td>(ii) reporting and evaluation on preparedness;</td>
</tr>
</tbody>
</table>

Justification

The proposal here to include auditing conflicts with Article 168 of the Treaty on the Functioning of the European Union, as healthcare systems remain the responsibility of Member States. Therefore, it is better to use "evaluation" which helps the Member States in audit their systems according to their specific circumstances.

Amendment 223
María Soraya Rodríguez Ramos, Jordi Cañas

Proposal for a regulation
Article 1 – paragraph 2 – point b a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(b a) a network of national strategic stockpiles and medical countermeasures</td>
<td></td>
</tr>
</tbody>
</table>

PE692.634v01-00 94/125 AM\1230399EN.docx
Amendment 224
Antoni Comín i Oliveres

Proposal for a regulation
Article 1 – paragraph 3

Text proposed by the Commission

3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.

Amendment

3. In order to honour the One Health approach and the Health in all policies principle, the implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments. The European Health Union, with its regulation on a reinforced mandate for the European Medicines Agency, and its regulation amending Regulation (EC) No 851/2004 establishing a European Centre for disease prevention and control, strengthen the Union health framework in order to address serious cross-border health threats, and shall be funded by the EU4Health programme. It shall be complementary to other Union policies and funds, namely, but not exclusively, actions implemented under the Horizon Europe, the Digital Europe Programme, ESIF, rescEU, ESI, ESF+, Next Generation EU, and SMP.

Amendment 225
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ștefan Motreanu, Cristian-Silviu Bușoi

Proposal for a regulation
Article 1 – paragraph 3
3. The implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments.

3. In keeping with "One Health" and "Health in all policies approaches", the implementation of this Regulation shall be supported by funding from relevant Union programmes and instruments. The strengthened Union health framework addressing serious cross-border health threats shall work in synergy with and in a manner that is complementary to other Union policies and funds, such as actions implemented under the ESIF, Horizon Europe, the Digital Europe Programme, rescEU, ESI, ESF+ and SMP.

Amendment 226
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 1 – paragraph 3 a (new)

Text proposed by the Commission

3 a. The implementation of this Regulation shall be carried out in full respect for the dignity and fundamental rights and freedoms of persons and shall ensure the “One health” and “Health in all Policies” approaches.

Amendment 227
Margarita de la Pisa Carrión

Proposal for a regulation
Article 1 – paragraph 3 a (new)

Text proposed by the Commission

3a. This Regulation shall ensure that in future health emergencies, the detection, health interventions and
treatment of other serious diseases are not halted.

Amendment 228
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. The implementation of this Regulation shall be with full respect for the dignity and fundamental rights and freedoms of persons.

Amendment 229
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 2 – paragraph 1 – point a – point i

Text proposed by the Commission

Amendment

(i) communicable diseases; (i) communicable diseases, including communicable diseases of zoonotic origin;

Amendment 230
Margrete Auken

Proposal for a regulation
Article 2 – paragraph 1 – point a – point i

Text proposed by the Commission

Amendment

(i) communicable diseases; (i) communicable diseases, including of zoonotic origin;
Amendment 231
Antoni Comín i Oliveres

Proposal for a regulation
Article 2 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission

(iii a) rare diseases of biological origin;

Amendment

Or. en

Amendment 232
Margarita de la Pisa Carrión

Proposal for a regulation
Article 2 – paragraph 1 – point c

Text proposed by the Commission

(c) threats of environmental or climate origin;

Amendment

deleted

Or. es

Amendment 233
Stanislav Polčák

Proposal for a regulation
Article 2 – paragraph 1 – point e

Text proposed by the Commission

(e) events which may constitute public health emergencies of international concern under the International Health Regulations (IHR), provided that they fall under one of the categories of threats set out in points (a) to (d).

Amendment

(e) events which may constitute public health emergencies of international concern under the International Health Regulations (IHR), provided that they fall under one of the categories of threats set out in points (a) to (d).

Or. cs
Amendment 234
Margarita de la Pisa Carrión

Proposal for a regulation
Article 2 – paragraph 1 – point e a (new)

Text proposed by the Commission

Amendment

(ea) This Regulation shall apply where an emergency situation is recognised, as set out in Article 23 of this Regulation.

Or. es

Amendment 235
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Buşoi

Proposal for a regulation
Article 2 – paragraph 2

Text proposed by the Commission

Amendment

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases, the surveillance of the impact of such diseases on non-communicable diseases and of related special health issues, such as mental health impacts of the crisis and the impact of deferred screening, diagnosis, monitoring, treatment and care for other diseases and conditions.

Or. en

Amendment 236
Antoni Comín i Oliveres

Proposal for a regulation
Article 2 – paragraph 2

Text proposed by the Commission

Amendment
2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues.

2. This Regulation shall also apply to the epidemiological surveillance of communicable diseases and of related special health issues, such as non-communicable diseases, or health consequences such as mental health conditions.

Amendment 237
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 2 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. This Regulation shall promote the implementation of the International Health Regulation, reduce administrative burden and duplication of resources, and strengthen the gaps unveiled from the COVID-19 pandemic in prevention, preparedness and response to public health threats.

Amendment 238
Joanna Kopcińska

Proposal for a regulation
Article 2 – paragraph 4

Text proposed by the Commission

Amendment

4. In exceptional emergency situations, a Member State or the Commission may request the coordination of response within the HSC as referred to in Article 21, for serious cross-border threats to health other than those referred to in Article 2(1), if it is considered that public health measures taken previously have proven insufficient to ensure a high
level of protection of human health. taken previously have proven insufficient to ensure a high level of protection of human health.

Justification

The current situation proves that in times of pandemics there are more problems with chronic diseases, including mental diseases, as for example the access to treatment is limited.

Amendment 239
Joanna Kopcińska

Proposal for a regulation
Article 2 – paragraph 5

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.</td>
<td>5. The Commission shall, in liaison with the Member States, ensure coordination and information exchange between the mechanisms and structures established under this Regulation and similar mechanisms and structures established at international level, Union level or under the Euratom Treaty whose activities are relevant for preparedness and response planning, monitoring, early warning of, and combating serious cross-border threats to health.</td>
</tr>
</tbody>
</table>

Justification

Links with WHO have to established as well to ensure synergies and avoid duplication of efforts.

Amendment 240
Antoni Comín i Oliveres

Proposal for a regulation
Article 2 – paragraph 6

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
</table>
6. Member States shall retain the right to maintain or introduce additional arrangements, procedures and measures for their national systems in the fields covered by this Regulation, including arrangements provided for in existing or future bilateral or multilateral agreements or conventions, on condition that such additional arrangements, procedures and measures do not impair the application of this Regulation.

Amendment 241
Margarita de la Pisa Carrión
Proposal for a regulation
Article 2 – paragraph 6 a (new)

Text proposed by the Commission

6a. The European Commission shall establish an electronic information system to ensure transparency, facilitate easy access for all EU citizens and combat disinformation.

Amendment

Or. en

Amendment 242
Stanislav Polčák
Proposal for a regulation
Article 3 – paragraph 1 – point 2

Text proposed by the Commission

(2) ‘communicable disease’ means an infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the

Amendment

2) ‘communicable disease’ means an infectious disease caused by a contagious agent which is transmitted from person to person by direct contact with an infected individual or by indirect means such as exposure to a vector, animal, fomite, product or environment, or exchange of fluid, which is contaminated with the
contagious agent; contagious agent, or from animal to human;

Amendment 243
Antoni Comín i Oliveres

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission

(3) ‘contact tracing’ means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of developing or have developed a disease, through manual or other technological means;

Amendment

(3) ‘contact tracing’ means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of developing or have developed a communicable or infectious disease, through manual or other technological means;

Or. en

Amendment 244
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 3 – paragraph 1 – point 3

Text proposed by the Commission

(3) ‘contact tracing’ means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of developing or have developed a disease, through manual or other technological means;

Amendment

(3) ‘contact tracing’ means measures implemented in order to trace persons who have been exposed to a source of a serious cross-border threat to health, and who are in danger of being infected, being infectious or have developed a disease, through manual or other technological means;

Or. en

Amendment 245
### Antoni Comín i Oliveres

Proposal for a regulation  
Article 3 – paragraph 1 – point 4

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(4) ‘epidemiological surveillance’ means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues;</td>
<td>(4) ‘epidemiological surveillance’ means the systematic collection, recording, analysis, interpretation and dissemination of data and analysis on communicable diseases and related special health issues as well as their impact on non-communicable diseases or health consequences such as mental health conditions;</td>
</tr>
</tbody>
</table>

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### Amendment 246
Margrete Auken

Proposal for a regulation  
Article 3 – paragraph 1 – point 5 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(5 a) ‘One Health’ is a collaborative, multi-sectoral, and transdisciplinary approach to designing and implementing programmes, policies, legislation and research in which multiple sectors communicate and work together to achieve better public health outcomes, recognising the interconnection between people, animals, plants, and their shared environment;</td>
<td></td>
</tr>
</tbody>
</table>

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### Amendment 247
Joanna Kopcińska

Proposal for a regulation  
Article 3 – paragraph 1 – point 7
(7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

Amendment

(7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin which spreads or entails a significant risk of coming from third countries to the territories of Member States and/or spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

Or. en

Justification

The current definition gives an impression of these threats could only originate from within the Member States.

Amendment 248
Stanislav Polčák

Proposal for a regulation
Article 3 – paragraph 1 – point 7

(7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

Amendment

(Does not affect the English version.)

Or. cs

Amendment 249
Margarita de la Pisa Carrión
Proposal for a regulation
Article 3 – paragraph 1 – point 7

Text proposed by the Commission

(7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical, environmental, climate or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

Amendment

7) ‘serious cross-border threat to health’ means a life-threatening or otherwise serious hazard to health of biological, chemical or unknown origin which spreads or entails a significant risk of spreading across the national borders of Member States, and which may necessitate coordination at Union level in order to ensure a high level of human health protection;

Or. es

Amendment 250
Joanna Kopcińska

Proposal for a regulation
Article 3 – paragraph 1 – point 7 a (new)

Text proposed by the Commission

(7 a) ‘major non-communicable disease’ means a disease as defined in point (4a) of Article 2 of Regulation (EU) [ECDC regulation, correct reference to be inserted];

Amendment

(7 a) ‘major non-communicable disease’ means a disease as defined in point (4a) of Article 2 of Regulation (EU) [ECDC regulation, correct reference to be inserted];

Or. en

Amendment 251
Stanislav Polčák

Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

(8 a) ‘International Health Regulations’ shall mean the International Health

Amendment

(8 a) ‘International Health Regulations’ shall mean the International Health

Amendment 252
Antoni Comín i Oliveres

Proposal for a regulation
Article 3 – paragraph 1 – point 8 a (new)

Text proposed by the Commission

Amendment

(8 a) ‘Health in all policies’ means health in all policies as defined in Regulation (EU) .../... EU 4 Health [OJ: ...]

Or. en

Amendment 253
Antoni Comín i Oliveres

Proposal for a regulation
Article 3 – paragraph 1 – point 8 b (new)

Text proposed by the Commission

Amendment

(8 b) ‘One Health approach’ means One health approach as defined in Regulation(EU) .../... EU 4 Health [OJ: ...]

Or. en

Amendment 254
Margrethe Auken

Proposal for a regulation
Article 4 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1 a. Representatives of the European
Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and the European Environment Agency (EEA) shall participate in HSC meetings as observers.

**Amendment 255**
Margarita de la Pisa Carrión

Proposal for a regulation
Article 4 – paragraph 2 – point a

Text proposed by the Commission

(a) enabling of coordinated action by the Commission and the Member States for the implementation of this Regulation;

Amendment

(a) enabling of coordinated action by the Commission and the Member States, including the national health authorities, for the implementation of this Regulation;

**Amendment 256**
Margrete Auken

Proposal for a regulation
Article 4 – paragraph 2 – point b

Text proposed by the Commission

(b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;

Amendment

(b) coordination in liaison with the Commission and relevant Union agencies of the preparedness and response planning of the Member States in accordance with Article 10;

**Amendment 257**
Margarita de la Pisa Carrión

Proposal for a regulation
Article 4 – paragraph 2 – point b
(b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;

(b) coordination in liaison with the Commission and the Member States of the preparedness and response planning of the Member States in accordance with Article 10;

Amendment 258
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 4 – paragraph 2 – point b

Text proposed by the Commission
(b) coordination in liaison with the Commission of the preparedness and response planning of the Member States in accordance with Article 10;

Amendment
(b) coordination in liaison with the Commission of the prevention, preparedness and response planning of the Member States in accordance with Article 10;

Or. es

Amendment 259
Margrete Auken

Proposal for a regulation
Article 4 – paragraph 2 – point c

Text proposed by the Commission
(c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

Amendment
(c) coordination in liaison with the Commission and relevant Union agencies of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

Or. en
Amendment 260
Margarita de la Pisa Carrión

Proposal for a regulation
Article 4 – paragraph 2 – point c

Text proposed by the Commission
(c) coordination in liaison with the Commission of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

Amendment
(c) coordination in liaison with the Commission and the Member States of the risk and crisis communication and responses of the Member States to serious cross-border threats to health, in accordance with Article 21;

Or. es

Amendment 261
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 2 – point d

Text proposed by the Commission
(d) adoption of opinions and guidance, including on specific response measures for the Member States for the prevention and control of serious cross-border threats to health.

Amendment
(Does not affect the English version.)

Or. cs

Amendment 262
Danilo Oscar Lancini

Proposal for a regulation
Article 4 – paragraph 2 – point d a (new)

Text proposed by the Commission

(d a) consultation with relevant third-party stakeholders, including healthcare professionals, patient groups and developers and manufacturers of medicinal products, on topics relevant to
the tasks of the Committee;

Amendment 263
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 2 – point d a (new)

Text proposed by the Commission

Amendment

(d a) support policies that guarantee the health in all policies principle and the One Health approach;

Or. en

Amendment 264
Joanna Kopcińska

Proposal for a regulation
Article 4 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission

The relevant Union agencies shall be involved in fulfilling the tasks of the HSC.

Or. en

Amendment 265
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 2 – point d b (new)

Text proposed by the Commission

Amendment

(d b) exchange good practices in order to make it easier for Member States to make the transition towards a healthcare model where aging and chronicity have gained relevance;
Or. en

Amendment 266
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 2 – point d c (new)

Text proposed by the Commission

(d c) strengthen public sector participation in health research strategies, in coherence with the Horizon Europe programme, in order to reinforce the necessary resources so that all strategic health research that cannot be done without public support may be carried out;

Or. en

Amendment 267
Stanislav Polčák

Proposal for a regulation
Article 4 – paragraph 4

Text proposed by the Commission

4. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

Amendment

4. The HSC shall be chaired by a representative of the Commission who shall have no voting rights. The Health Security Committee shall meet when the situation requires, on a request from the Commission or a Member State, as well as outside those intervals.

Or. cs

Amendment 268
Joanna Kopcińska

Proposal for a regulation
Article 4 – paragraph 4
4. The HSC shall be chaired by a representative of the Commission. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

Amendment

4. The HSC shall be chaired by a representative of the Commission without the right to vote. The HSC shall meet at regular intervals and whenever the situation requires, on a request from the Commission or a Member State.

Or. en

Justification

The Commission should organise the work of HSC, call its meetings when it considers necessary and provide assistance, but it should be clear that only the representatives of the Member States should vote.

Amendment 269
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 5

Text proposed by the Commission

5. The secretariat shall be provided by the Commission.

Amendment

5. The secretariat shall be provided by the Commission and shall be instituted within the competent directorate general of the Commission.

Or. en

Amendment 270
Margrete Auken

Proposal for a regulation
Article 4 – paragraph 5 a (new)

Text proposed by the Commission

5 a. Members of the Committee and the Commission shall ensure thorough consultation with relevant Union agencies, public health experts, international organisations and stakeholders, including healthcare
professionals.

Amendment 271
Margarita de la Pisa Carrión
Proposal for a regulation
Article 4 – paragraph 6 – introductory part

Text proposed by the Commission

6. The HSC shall adopt, by a majority of two thirds of its members, its rules of procedure. Those rules of procedure shall establish working arrangements, in particular with regard to:

Amendment

6. The HSC shall adopt, by a majority of two thirds of its members, its rules of procedure. Those rules of procedure shall establish working arrangements and competences without prejudice to the principle of proportionality and subsidiarity, in particular with regard to:

Or. es

Amendment 272
Stanislav Polčák
Proposal for a regulation
Article 4 – paragraph 6 – point b

Text proposed by the Commission

(b) the participation of experts in plenary meetings at high level, the status of possible observers, including from third countries;

Amendment

(b) the participation of experts in plenary meetings, the status of possible observers, including from third countries;

Or. cs

Amendment 273
Antoni Comín i Oliveres
Proposal for a regulation
Article 4 – paragraph 7 – introductory part
7. Member States shall designate one representative and not more than two alternate members of the HSC in each working formation referred to in paragraph 1.

7. Member States shall designate one representative and not more than two alternate members of the HSC in each working formation referred to in paragraph 1. Member States shall designate their representatives and alternate members within 30 days after the entry into force of this Regulation. In case a representative or an alternate representative cedes her or his responsibilities within the HSC, the Member State shall designate a substitute or substitutes within 30 days.

Or. en

Amendment 274
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 7 – subparagraph 1 a (new)

Text proposed by the Commission

In case the Member State has not designated any substitute within 30 days after the termination of the previous representative or alternate member, the HSC shall nevertheless continue its undertakings after an official letter sent to the Member State by the Chair of the HSC.

Or. en

Amendment 275
Kateřina Konečná

Proposal for a regulation
Article 4 – paragraph 7 – subparagraph 1 a (new)

Recognised European social partners in the relevant EU sectoral social dialogue
committees in the health and social services and the representative of patient's organizations shall have observer status in the HSC.

Amendment 276
Antoni Comín i Oliveres

Proposal for a regulation
Article 4 – paragraph 7 – subparagraph 1 b (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>The European Parliament shall nominate two observers, elected by its Committee on Environment, Public Health and Food Safety. These observers shall be elected during the European Parliament’s mandate. Each observer shall be elected for a maximum of five years.</td>
<td></td>
</tr>
</tbody>
</table>

Amendment 277
Margrete Auken

Proposal for a regulation
Article 4 – paragraph 7 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>7 a. The list of members of the Health Security Committee at both the political and technical levels shall be made public on the Commission and Council websites. Members of the Committee must have no financial or other interests that could affect their impartiality. They shall act in the public interest and in an independent manner and make an annual declaration of their financial interests. All indirect interests which could relate to the medical or other relevant industry shall be entered in a register held by the Commission and</td>
<td></td>
</tr>
</tbody>
</table>
be accessible to the public, upon request.

Or. en

Amendment 278
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 4 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

7 a. The European Parliament shall designate representatives to participate in the Health Security Committee (HSC) as observers.

Or. en

Amendment 279
Margrete Auken

Proposal for a regulation
Article 4 – paragraph 7 b (new)

Text proposed by the Commission

Amendment

7 b. The rules of procedure, guidance, agendas and minutes of the meetings of the HSC shall be published on the Commission’s web-portal. To allow further public scrutiny by the European Parliament, the Commission shall be invited for an annual exchange of view regarding the work of the HSC with the Committee on the Environment, Public Health and Food Safety (ENVI).

Or. en

Amendment 280
Kateřina Konečná

Proposal for a regulation
Chapter II – title

Text proposed by the Commission

Amendment

II PREPAREDNESS AND RESPONSE PLANNING

II PREVENTION,
PREPAREDNESS AND RESPONSE PLANNING

Cross-border threats from within the EU need to be prevented where possible. ‘Preparedness and Response’ planning is too reactive and not sufficiently proactive.

Amendment 281
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Bușoi

Proposal for a regulation
Chapter II – title

Text proposed by the Commission

Amendment

II PREPAREDNESS AND RESPONSE PLANNING

II PREVENTION,
PREPAREDNESS AND RESPONSE PLANNING

Amendment 282
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Chapter II – title

Text proposed by the Commission

Amendment

II PREPAREDNESS AND RESPONSE PLANNING

II PREVENTION,
PREPAREDNESS AND RESPONSE PLANNING
Amendment 283
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 5 – title

Text proposed by the Commission
Union preparedness and response plan

Amendment
Union prevention, preparedness and response plan

Or. en

Amendment 284
Joanna Kopcińska

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission
1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan (‘the Union preparedness and response plan’) to promote effective and coordinated response to cross-border health threats at Union level.

Amendment
1. The Commission, in cooperation with Member States and the relevant Union agencies and taking into account the WHO framework, shall establish a Union health crisis and pandemic plan (‘the Union preparedness and response plan’) to promote effective and coordinated response to cross-border health threats at Union level.

Or. en

Amendment 285
Kateřina Konečná

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission
1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan (‘the Union preparedness and response plan’) to

Amendment
1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan (‘the Union prevention, preparedness and response plan’) to
promote effective and coordinated response to cross-border health threats at Union level.

Amendment 286
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 5 – paragraph 1

Text proposed by the Commission

1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan (‘the Union preparedness and response plan’) to promote effective and coordinated response to cross-border health threats at Union level.

Amendment

1. The Commission, in cooperation with Member States and the relevant Union agencies, shall establish a Union health crisis and pandemic plan (‘the Union prevention, preparedness and response plan’) to promote effective and coordinated response to cross-border health threats at Union level.

Amendment 287
Antoni Comín i Oliveres

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

Amendment

2. The Union preparedness and response plan shall complement the national and regional preparedness and response plans established in accordance with Article 6.

Amendment 288
Kateřina Konečná
Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

Amendment

2. The Union prevention, preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

Or. en

Amendment 289
Stanislav Polčák

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission

2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

Amendment

2. The Union preparedness and response plan shall complement the national preparedness and response plans established in accordance with Article 6.

Or. cs

Amendment 290
Kateřina Konečná

Proposal for a regulation
Article 5 – paragraph 3 – introductory part

Text proposed by the Commission

3. The Union preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

Amendment

3. The Union prevention, preparedness and response plan shall, in particular, include arrangements for governance, capacities and resources for:

Or. en

Amendment 291
Antoni Comín i Oliveres

Proposal for a regulation
Article 5 – paragraph 3 – point a

Text proposed by the Commission

(a) the timely cooperation between the Commission, the Member States and the Union agencies;

Amendment

(a) the timely cooperation between the Commission, the Member States, regions with health competences, and the Union agencies;

Or. en

Amendment 292
Antoni Comín i Oliveres

Proposal for a regulation
Article 5 – paragraph 3 – point b

Text proposed by the Commission

(b) the secure exchange of information between the Commission, Union agencies and the Member States;

Amendment

(b) the secure exchange of information between the Commission, Union agencies, regions with health competences, and the Member States;

Or. en

Amendment 293
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colin-Oesterlé, Cristian-Silviu Bușoi

Proposal for a regulation
Article 5 – paragraph 3 – point b a (new)

Text proposed by the Commission

(b a) the mapping of the strategic production capacities for the Union as a whole;

Amendment

(b a) the mapping of the strategic production capacities for the Union as a whole;

Or. en
Amendment 294
Antoni Comín i Oliveres

Proposal for a regulation
Article 5 – paragraph 3 – point c

Text proposed by the Commission
(c) the epidemiological surveillance and monitoring;

Amendment
(c) the epidemiological surveillance and monitoring, as well as the impact of communicable diseases on non-communicable diseases;

Or. en

Amendment 295
Esther de Lange, Peter Liese, Adam Jarubas, Marlene Mortler, Dolors Montserrat, Alexander Bernhuber, Nathalie Colín-Oesterlé, Dan-Ştefan Motreanu, Cristian-Silviu Bușoi

Proposal for a regulation
Article 5 – paragraph 3 – point c a (new)

Text proposed by the Commission
(c a) the continuity of screening, diagnosis, monitoring, treatment and care for other diseases and conditions during health emergencies;

Amendment
Or. en

Amendment 296
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 5 – paragraph 3 – point e

Text proposed by the Commission
(e) the risk and crisis communication;

Amendment
(e) the risk and crisis communication, for health professionals and for citizens;

Or. en
Amendment 297
Stanislav Polčák

Proposal for a regulation
Article 5 – paragraph 3 – point f

Text proposed by the Commission

(f) the health preparedness and response and intersectoral collaboration;

Amendment

(f) the health preparedness and response and intersectoral collaboration, including between the health and veterinary sectors in cases of cross-border zoonotic health threats;

Or. cs

Amendment 298
Nathalie Colin-Oesterlé

Proposal for a regulation
Article 5 – paragraph 3 – point g a (new)

Text proposed by the Commission

(ga) the establishment of a European stock of critical medicines and medical countermeasures as part of the rescEU emergency reserve;

Amendment

Or. fr

Amendment 299
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 5 – paragraph 3 – point g a (new)

Text proposed by the Commission

(g a) the continuity of healthcare services, particularly for chronic conditions;

Amendment

Or. en
Amendment 300
Kateřina Konečná

Proposal for a regulation
Article 5 – paragraph 3 – point g a (new)

Text proposed by the Commission

Amendment

(g a) adequate and needs-oriented staffing level;

Or. en

Amendment 301
Kateřina Konečná

Proposal for a regulation
Article 5 – paragraph 3 – point g b (new)

Text proposed by the Commission

Amendment

(g b) adequate stock of personal protective equipment of the highest quality;

Or. en

Amendment 302
Sara Cerdas, César Luena, Monika Beňová, Petar Vitanov, Javi López, Sándor Rónai

Proposal for a regulation
Article 5 – paragraph 3 – point g b (new)

Text proposed by the Commission

Amendment

(g b) the criteria to activate and deactivate the plan.

Or. en